

HOUSE BILL 1465

By Harwell

AN ACT to amend Tennessee Code Annotated, Title 53, Chapter 10, Part 1 and Title 63, Chapter 10, relative to the distribution and dispensing of certain legend drugs.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Title 53, Chapter 10, Part 1, is amended by adding the following language as a new section:

§ 53-10-111.

(a) This part shall not apply to a person, firm or corporation, including a drug manufacturer, hospital, or government agency, who donates or otherwise gives away a legend drug if:

(1) Such drug is distributed, donated or given to an organization that is exempt from federal income taxation under § 501(a) of the Internal Revenue Code as an organization described in § 501(c)(3) of the Internal Revenue Code;

(2) The primary purpose of such nonprofit organization is to collect legend drugs donated by another person, firm or corporation and distribute or dispense such drugs to persons who earn less than two hundred percent (200%) of the federal poverty level and who have a medical need for such drugs;

(3) Such drug is only dispensed by a pharmacist or pharmacy licensed by the Tennessee board of pharmacy;

(4) The nonprofit organization does not accept or distribute any donated drug that is classified and scheduled as a controlled substance pursuant to title 39, chapter 17, part 4; and

(5) Any legend drug so distributed, donated or given to such nonprofit organization is:

(A) In solid form;

(B) Not misbranded, out of date or deteriorated;

(C) Unopened and in its original packaging, including a drug packaged in single-unit doses and blister packs; and

(D) Not obviously tampered with, adulterated, or damaged.

(b) Before any legend drug is dispensed to a person pursuant to this section, the nonprofit organization shall require the intended recipient or the intended recipient's representative to give written, informed voluntary consent for the use of such drug.

(c) A good-faith donor of any legend drug meeting the requirements of subsection (a) for free distribution is not subject to:

(1) Criminal prosecution for a violation of this part;

(2) License revocation or suspension; or

(3) Civil liability arising from the condition of the drug, unless the proximate cause of an injury is the gross negligence, recklessness or intentional misconduct of the donor.

(d) A nonprofit organization as specified in subsection (a) that in good faith accepts, donates, distributes or dispenses any legend drug in compliance with this section, is not subject to:

(1) Criminal prosecution for a violation of this part; or

(2) Civil liability arising from the condition of the drug, unless the proximate cause of an injury is the gross negligence, recklessness or intentional misconduct of the organization.

SECTION 2. This act shall take effect July 1, 2009, the public welfare requiring it.